Notice of Allowability	Application No.	Applicant(s)	
	09/803,778	MAPLESON ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *interview on 2-5-07*.

2. ☒ The allowed claim(s) is/are *1-5, 7-8, 14-16 and 19 now renumbered claims 1-12 respectively.*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☒ Certified copies of the priority documents have been received in Application No. *09/463,762* .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ROBERT A. ZEMAN
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles E. Bell on 2-5-2007.

The application has been amended as follows:

In the Claims:

Claims 1-5, 7-8, 14-17 and 19 were replaced with the following:

1. A method of removing bacterial endotoxin from a pharmaceutical process solution containing an amphiphilic pharmaceutical drug or vaccine, wherein said method comprises:

a) treating the pharmaceutical process solution with a concentration of sodium deoxycholate that is effective to dissociate the endotoxin from the amphiphilic pharmaceutical drug or vaccine in the pharmaceutical process solution without affecting the ability of the drug or vaccine to be retained by a molecular cut-off filter having a pore size effective to retain the amphiphilic pharmaceutical drug or vaccine substance but allow the disassociated bacterial endotoxin to pass through;

b) directly thereafter filtering the treated pharmaceutical process solution though a 30 kDa molecular weight cut-off filter; and

c) thereafter, subjecting the filtered pharmaceutical process solution to a further process step in which the sodium deoxycholate is removed, wherein after this process step the amount of sodium deoxycholate remaining in the pharmaceutical process solution is less than 0.002%.

2. The method according to claim 1, wherein the amphiphilic pharmaceutical drug or vaccine comprises a polypeptide.

3. The method according to claim 2, wherein the amphiphilic pharmaceutical drug or vaccine comprises a glycoprotein.

4. The method according to claim 1, wherein the amphiphilic pharmaceutical drug or vaccine is an antigen.

5. The method according to claim 4, wherein the antigen is a viral antigen.

7. The method according to claim 5, wherein the antigen is an influenza antigen.

8. The method according to claim 5, wherein the antigen is a haemagglutinin and/or neuramidase antigen.

14. The method according to claim 1, wherein the concentration of the sodium deoxycholate added in step a) is at least as great as its critical micelle concentration.

15. The method according to claim 14, wherein the concentration of the sodium deoxycholate added in step a) is from one and a half to five times its critical micelle concentration.

16. The method according to claim 14, wherein the concentration of the sodium deoxycholate added in step a) is from two to four times its critical micelle concentration.

17. The method according to claim 1, wherein the molecular weight cut-off filter comprises a regenerated cellulose acetate membrane, or a polysulfone membrane.

19. The method according to claim 1, wherein the further process step comprises subjecting the filtered pharmaceutical process solution to dialysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ROBERT A. ZEMAN
PRIMARY EXAMINER

February 5, 2007